

Notice of Allowability

Application No.

09/869,540

Examiner

Dong Jiang

Applicant(s)

MORI ET AL.

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the supplemental amendment filed on 8/3/04.
2. ☒ The allowed claim(s) is/are 1, 2 and 12-14 to issue as 1, 4, 3, 2 and 5, respectively.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☒ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☒ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

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DETAILED OFFICE ACTION

Applicant's supplemental amendment filed on 03 August 2004 is acknowledged and entered. Following the amendment, claims 1, 2 and 12-14 are amended.

Currently, claims 1, 2 and 12-14 are pending and under consideration.

The declaration under 37 CFR 1.132 filed on 03 August 2004 is sufficient to overcome the rejection of claims 1, 2 and 12-14 based upon the prior art references by Ames et al., US 2002/0038007, in view of Maratos-Flier, US 5,849,708, and Bolton et al. (Biochem. J., 1973, 133:529-539), and the prior art references by Salon et al, US 6,221,616 B1, in view of Maratos-Flier, US 5,849,708, and Bolton et al. (Biochem. J., 1973, 133:529-539).

Withdrawal of Objections and Rejections:

The rejection of claims 2 and 14 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in view of applicant's amendment.

The prior art rejections of claims 1, 2 and 12-14 under 35 U.S.C. 103(a) made in the Office Action is withdrawn in view of applicant's declaration and argument.

Examiner's Comment

New formal drawings in compliance with 37 CFR 1.121(d) are required in this application because it lacks formal drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance. Applicant is hereby given **ONE MONTH** from the mailing date of "Notice of Allowability" (PTOL-37 or PTO-37) to file corrected drawings.

Examiner's Statement of Reasons for Allowance

The following is an examiner's statement of reasons for allowance: claims 1, 2 and 12-14 of the present invention are directed to a method for screening a compound using [¹²⁵I][N-(3-(4-hydroxy 3-iodophenyl)propionyl)-Met⁴]-MCH(4-19) or BH-MCH(4-19). The compound

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identified by the method would be useful in modulating appetite. The prior art search results reveal that SLC-1/MCH receptor-ligand (a hormone) are known in the art, that MCH agonists lacking residues 1-4 are equipotent to native MCH as to the functional activity, and that Bolton-Hunter reagent is known to be used for labeling proteins to high specific radioactivities for compound screening. Therefore, it would have been obvious to the person of ordinary skill in the art at the time the invention was made to label MCH(4-19) as well as the other possible MCH fragments suggested by the prior art with a Bolton-Hunter reagent for the purpose of identifying agonist or antagonist of the receptor in a screening method, and the person of ordinary skill in the art would have been motivated to make such a labeled peptide for identifying the compounds having potential therapeutic uses, and reasonably would have expected success because BH agent has been successfully used for labeling of several hormone peptides.

In the declaration by Masaaki Mori filed on 03 August 2004, the applicant presents experimental data to demonstrate that the agonist activity of MCH and fragments MCH(2-19), MCH(3-19), MCH(4-19), and MCH(5-19) are comparable (Example 21 and Figure 7 of the specification, and the data summary table on page 8 of the declaration), and that with the exception of MCH(4-19), the agonist activity of the derivatized MCHs (BH-MCHs) is reduced comparing to their underivatized counterparts (Example 22, Figure 8 of the specification, and the data summary table on page 5 of the declaration). The derivatized MCH(4-19) showed even higher agonist activity than that of BH-MCH (full length), which is concluded in the declaration as *unexpected* result. This is persuasive, and therefore, the declaration under 37 CFR 1.132 filed on 03 August 2004 is sufficient to overcome the prior art rejections of claims 1, 2 and 12-14 under 35 U.S.C. 103(a) as none of the prior art references has taught or suggested that BH-MCH(4-19) would have higher functional activity, which makes BH-MCH(4-19) distinct from other derivatized MCH fragments.

Conclusion:

Claims 1, 2 and 12-14 are allowed.

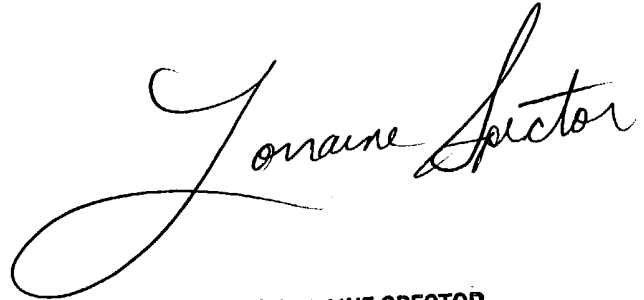
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Advisory Information:

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Dong Jiang, Ph.D.
Patent Examiner
AU1646
9/8/04

A handwritten signature in black ink that reads "Lorraine Spector". The signature is written in a cursive, flowing style with a large initial "L".

**LORRAINE SPECTOR
PRIMARY EXAMINER**